

REMARKS

Applicants filed an Amendment and Response (“the Amendment”) on November 27, 2007, in reply to the final Office Action dated December 27, 2006. In reply to Applicants’ Amendment, the Patent Office issued a Notice of Non-Compliant Amendment, stating that the version of amended Claim 31 includes stricken/deleted text that does not correspond to the previous version of the claims dated October 6, 2006. In the instant amendment, this informality has been corrected. The content of this amendment is otherwise substantially identical to that of the amendment filed November 27, 2007. It is believed that the instant amendment fully complies with the requirements under 37 C.F.R. § 1.121. Also a Request for Continued Examination was filed with the Amendment on November 27, 2007. Thus, Applicants respectfully request entry of this amendment and consideration of the remarks presented herein.

In the instant amendment, Claims 31, 38 and 40 have been amended. Claims 33-37 and 39 have been canceled without prejudice. Claims 41-53 have been added. After entry of the instant amendment, Claims 31-32 and 40-53 will be pending and under consideration.

I. THE AMENDMENTS TO THE CLAIMS

In the instant amendment, Claims 33-37 and 39 have been canceled without prejudice to Applicants’ right to pursue the canceled subject matter in one or more related patent applications.

Claims 31, 38 and 40 have been amended. Support for the amendments to Claim 31 can be found in the specification, for example, in paragraph [00030] at page 9, paragraph [00088] at page 26, and paragraphs[00098]-[00099] at pages 29-30. Support for the amendments to Claim 38 can be found in the specification, for example, in paragraph [00030] at page 9. Support for the amendments to Claim 40 can be found in the specification, for example, in paragraph [00022] at page 6.

Claims 41-53 have been added. Support for new Claim 41 can be found in the specification, for example, in paragraph [00092] at page 27. Support for new Claims 42-44 can be found in the specification, for example, in paragraphs [00098]-[00099] at pages 29-30, and at paragraphs [00164]-[00165] at pages 49-50. Support for new Claim 45 can be found in the specification, for example, in paragraph [00094] at page 45. Support for Claims 46-47 can be found in the specification, for example, in paragraph [00152] at page 44, Table 2 at

page 45, paragraph [00147] at page 46, and Table 4 at page 47. Support for Claim 48 can be found in the specification, for example, in paragraph [00093] at page 27. Support for Claim 49 can be found in the specification, for example, in paragraphs [00094]-[00095] at pages 27-28. Support for Claims 50-51 can be found in the specification, for example, in paragraph [00154] and Table 3 at page 45, paragraph [00159] at page 47, and Table 5 at pages 47-48. Support for Claim 52 can be found in the specification, for example, in paragraph [00033] at page 10, paragraph [00100] at page 30, and paragraph [00167] at page 50. Support for Claim 53 can be found in the specification, for example, in paragraph [00030] at page 9, paragraph [00088] at page 26, and paragraphs [00098]-[00099] at pages 29-30.

Applicants respectfully submit that the amendments to the claims do not introduce any new matter and are fully supported by the specification and claims as originally filed. Entry and consideration of the amendments are respectfully requested.

II. THE REJECTION OF CLAIMS 31-40 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

A. The rejection of Claims 31-40 for Lack of Enablement

Claims 31-40 stand rejected under 35 U.S.C. § 112, first paragraph for alleged lack of enablement. Specifically, the Patent Office alleges that the specification does not reasonably provide enablement for a method of diagnosing predisposition to obesity or central obesity in human subject by detecting any polymorphic variation associated with obesity at position 7328 or 9182, or a G at position 7328, or a T at position 9182 in a nucleotide sequence identical to or 99% identical to SEQ ID NO:1 in a nucleic acid sample from a subject. *See* the Office Action, page 2. The Patent Office acknowledges that the specification is enabled for a method of diagnosing leanness in an a human subject comprising detecting the presence of an A at position of 7328 of SEQ ID NO:1 or a G at position 9182 of SEQ ID NO:1. *See* the Office Action, page 2. *See id.*

Claim 31 has been amended to recite, in relevant part, a method for determining whether a subject is at decreased risk of fat deposition comprising (a) detecting the presence or absence of an A allele at position 7328 of a PLA2G1B nucleic acid comprising the sequence of SEQ ID NO: 1 or a T allele at its complementary position in a strand complementary to SEQ ID NO:1 in a nucleic acid sample from the subject, or (b) detecting the presence or absence of a G allele at position 9182 of a PLA2G1B nucleic acid comprising the sequence of SEQ ID NO: 1 or a C allele at its complementary position in a strand

complementary to SEQ ID NO:1 in a nucleic acid sample from the subject. As acknowledged by the Patent Office, the specification teaches that the two recited alleles are associated with reduced fat deposition and thus is enabled for the claimed method. Thus, Applicants respectfully submit that the specification is enabled for amended Claim 31 and its dependent claims.

B. The rejection of Claims 31-40 for Lack of Written Description

Claims 31-40 stand rejected allegedly for failure to comply with the written description requirement under 35 U.S.C. § 112, first paragraph. Specifically, the Patent Office contends that the specification does not provide sufficient written support for the claimed method allegedly because the genus of sequences encompassed by the claims include any polymorphic variation associated with obesity at position 7328 or 9182 in a nucleotide sequence identical to SEQ ID NO:1, and any polymorphic variation in a nucleotide sequence 99% identical to SEQ ID NO:1 and the specification teaches that only two particular alleles are associated with reduced fat deposition. *See* the Office Action, pages 9-13.

Claim 31 has been amended as discussed in detail above. Applicants respectfully submit that the specification provides sufficient written support for amended Claim 31 and its dependent claims.

In view of the foregoing, the withdrawal of the rejection of Claims 31-40 under 35 U.S.C. § 112, first paragraph is respectfully requested.

III. THE REJECTION OF CLAIMS 31-33 AND 38-40 UNDER 35 U.S.C. § 103

Claims 31-33 and 38-40 stand rejected under 35 U.S.C. § 103, allegedly as being obvious over GenBank Accession number AY 438977 in view of U.S. Pat. No. 6,023,431 by Soderlund *et al.* (“Soderlund *et al.*”). Applicants respectfully submit that Claims 31-33 and 38-40 as amended are not obvious in view of the cited references.

A. Legal Standard

The U.S. Supreme Court has recently addressed the test for obviousness under 35 U.S.C. § 103. *KSR International Co. v. Teleflex Inc.*, No. 04-1350, 550 U.S. __ (2007). In *KSR*, the Supreme Court rejected the Federal Circuit's *rigid application* of the "teaching, suggestion, motivation" test (“the TAM test”) in determining obviousness in the particular case in question. *Id.*, *slip op.* p. 11. According to the Supreme Court, the correct standard to

apply is set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966). *Id.*, *slip op.* p. 2. However, the *KSR* decision indicated that while the TAM test is not the sole method for determining obviousness, it may still be a factor. *Id. slip op.* p. 14 (“When it first established [the TAM test], the Court . . . captured a helpful insight.”). Indeed, on May 3, 2007, the Deputy Commissioner of Patents circulated a memorandum (“USPTO Memorandum,” copy enclosed) to the Technology Center Directors pointing out that the TAM test was not completely abolished in *KSR*.

The *Graham* factual inquiries, which establish a guide for determining obviousness, are: (1) determine the scope and contents of the prior art; (2) ascertain the differences between the prior art and the claims at issue; (3) resolve the level of ordinary skill in the pertinent art; and (4) evaluate any evidence of secondary considerations. *KSR, slip op.* p. 2 (*citing Graham*, 383 U.S. at 15-17).

B. Rejection of Claims 31-33 and 38-40 Should be Withdrawn

Claim 31 has been amended to recite, in relevant part, a method for determining whether a subject is at decreased risk of fat deposition comprising detecting the presence or absence of a particular allele, *i.e.*, an A allele at position 7328 or a G allele at position 9182 of a PLA2G1B nucleic acid comprising the sequence of SEQ ID NO: 1, wherein the presence of the allele(s) indicates the subject is at decreased risk of fat deposition.

Applicants respectfully submit that amended Claim 31 and its dependent claims are not obvious in view of the cited references. First, the cited references differ substantially from the subject matter of the instant claims since either reference teaches or suggest a method for determining whether a subject is at decreased risk of fat deposition comprising detecting the presence or absence of a particular allele of a PLA2G1B nucleic acid. GenBank Accession number AY 438977 discloses the sequence of PLA2G1B and the polymorphisms at positions corresponding to position 7328 or 9182 of SEQ ID NO:1. However, GenBank Accession number AY 438977 does not teach or suggest that the presence of the recited allele(s) would be indicative of a subject’s risk of fat deposition. It does not teach or suggest a method for determining whether a subject is at decreased risk of fat deposition by detecting the presence of the recited allele(s). Therefore, substantial differences exist between the teaching in GenBank Accession number AY 438977 and the claimed invention. Because of such substantial differences, the instant claims as amended are not obvious.

Further, the Patent Office has not provided a reason why one of ordinary skill in the art would modify the teachings of GenBank Accession number AY 438977 to arrive at the claimed method. Soderlund *et al.* discloses a method of detecting nucleotide variation. Soderlund *et al.* does not teaches or suggest how to correlate a particular polymorphism with a phenotype or the particular correlation between the recited alleles and a subject's decreased risk of fat deposition. Because the reference cited by the Patent Office does not disclose each element of the instant claims, the Patent Office must articulate a reason why one of ordinary skill in the art would correlate. *KSR, slip op.* p. 15; *see also* USPTO Memorandum. Because the Patent Office has not met this burden, the instant claims as amended are not obvious.

In view of the foregoing, Applicants respectfully request the rejection of Claims 13 and 22-32 over GenBank Accession number AY 438977 in view of Soderlund *et al.* under 35 U.S.C. § 103(a) be withdrawn.

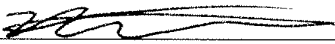
CONCLUSION

In light of the above amendments and remarks, the Applicants respectfully request that the Patent Office reconsider this application with a view towards allowance.

The Commissioner is hereby authorized to charge any required fee to Jones Day Deposit Account No. 50-3013 (order no. 167471-999009).

Respectfully submitted,

Date: May 30, 2008


Rahul Pathak 42,983
(Reg. No.)
For: Anthony M. Insogna (Reg. No. 35,203)

JONES DAY
222 East 41st Street
New York, New York 10017
(212) 326-3939